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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,687	09/28/2000	David Wallach	WALLACH=25	7238

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/671,687	Applicant(s) WALLACH ET AL.	
	Examiner David A. Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.  
 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-4, 20-24, 38-40 and 42-48 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 2, 4, 20-24, 38 and 44-46 is/are rejected.  
 7) ☒ Claim(s) 3, 39, 40, 42, 43, 47 and 48 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☒ Certified copies of the priority documents have been received in Application No. 09/646,403.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed March 28, 2005.

Claims 2-4, 20-24, 38-40 and 42-48 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed October 1, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

The information disclosure statement filed November 26, 2004 has been considered, and a signed and initialed copy of the form PTO-1449 has been attached to this Office Action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 2, 4, 20 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase (as recited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

***Response to Arguments Concerning Claim Rejections - 35 USC § 102***

Applicant's arguments filed March 28, 2005 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

1. Applicant contends that Nagase is not available as prior art considering the disclosure in foreign priority document IL126024 of clone #10. Clone #10 is a nucleotide sequence for a partial polypeptide later identified as instantly claimed SEQ ID NO: 3 (i.e., a specific fragment of SEQ ID NO: 3). As such, Applicant argues that the foreign priority document contains literal support for claim 2, subpart (c), which is directed to *all possible* fragments of SEQ ID NO: 3 (see for example the bottom paragraph of page 2 of Applicant's response).

Applicant's arguments are not persuasive for the following reasons:

1. The question of foreign priority is a question of Written Description; in other words, the full scope of the claim must be described in the priority document in order for the full scope of the claim to be granted priority. In the instant case, claim 2(c) is directed to *any* fragment of SEQ ID NO: 3, and is not limited to a particular fragment (such as that described by clone #10 of foreign priority document IL126024). Foreign priority document IL126024 only discloses clone #10 as it relates to the instantly claimed invention; it is important to note that IL126024 fails to actually describe the partial polypeptide within clone #10 (i.e., identification of reading frame, where the actual protein encoded by SEQ ID NO: 3 as it relates to the instant invention, etc.). Furthermore,

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Applicant acknowledges that this is merely a partial sequence of instant SEQ ID NO: 3, and therefore IL126024 cannot provide literal support for the full scope of the claimed invention. Indeed, clone #10 as disclosed in foreign priority document IL126024 only comprises a sequence beginning with amino acid 548 of instantly claimed SEQ ID NO: 3 (as deduced by the examiner), and there is no disclosure as to the nature of the rest of the polypeptide or the nucleotide sequence encoding said polypeptide. Thus, Applicant does not provide a written description for the full scope of the claim, and therefore cannot be granted foreign priority for said scope.

It is also important to note that Nagase discloses a sequence that is 100% identical to amino acids 446-949 of instantly claimed SEQ ID NO: 3. Thus, Nagase discloses a polypeptide sequence that is in fact *not* disclosed in foreign priority document IL126024 because it describes amino acids that are a part of instantly claimed SEQ ID NO: 3 but are *not* described in the foreign priority document. Applicant is invited to indicate where in IL126024 there is a teaching of the identity of residues 446-597 of instantly claimed SEQ ID NO: 3, such that the skilled artisan would understand they were in possession of the fragment taught by Nagase, if such a teaching exists.

Given the fact that Applicant has not provided a written description for the full scope of claim 2 (c) within foreign priority document IL126024 (absent evidence to the contrary), claim 2 is *not* granted priority to IL126024. Thus, Nagase remains available as prior art as it regards subpart (c) of claim 2, and dependent claims thereof.

It is additionally noted that the instant application has a filing date of September 28, 2000, which is greater than one year prior to the foreign priority date of IL126024. Furthermore,

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it is noted that US priority application 09/646,403 fails to disclose SEQ ID NO: 3 (as indicated in the previous Office Action, and for which no argument is provided), and thus also lacks literal support as a priority document for SEQ ID NO: 3. Thus, IL126024 is unavailable as a foreign priority reference for the instant application because it is more than one year prior to the effective filing date for claim 2 (c) of the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagase (as applied to claims 2, 4, 20 and 38) in view of Applicant's admission in the paper filed September 23, 2002 (see for example pages 2-6) that it would be obvious for one of skill in the art to make antibodies to a protein that is known in the prior art. **This rejection is maintained for the reasons set forth in the previous Office Action.**

***Response to Arguments Concerning Claim Rejections - 35 USC § 102***

Applicant's arguments filed March 28, 2005 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

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1. Applicant argues that Nagase is unavailable as prior art, and therefore is ineligible for use in an obviousness rejection (see for example the third full paragraph of page 4 of Applicant's response).
2. Applicant argues that the examiner has misinterpreted the admission of the paper filed September 23, 2002. Applicant indicates that the admission was only with regard to a protein with a known biological function/property, and argues that Nagase fails to teach a biological function for the predicted amino acid sequence indicated as KIAA0849. Applicant then argues that, in the absence of a biological function for KIAA0849, the ordinary skilled artisan would not have motivation to generate antibodies against said protein.

Applicant's arguments have been fully considered but are not found convincing for the following reasons:

1. As set forth above in the arguments concerning the rejections under 35 USC § 102(b), Nagase is available as prior art because foreign priority document IL126024 fails to provide written description in support of the full scope of claim 2 (c), including the specific polypeptide disclosed by Nagase. Thus, Nagase is an acceptable reference for formulation of a rejection under 35 USC § 103(a), and cannot be a persuasive grounds for traversal of such a rejection.
2. With regard to Applicant's admission, there is no specific definition as to what represents a "biological function" or "biological property" as it relates to motivation for making an antibody to a protein. Thus, the terms "biological function" or "biological property" must be interpreted broadly, and thus includes the tissue-specific expression of a gene/protein. Therefore, Nagase clearly teaches a "biological function/property" for KIAA0849 in the broadest reasonable

interpretation of the term "biological function/property" as set forth in Applicant's admission, which is the expression of KIAA0849 in the brain. Given this "biological property," the ordinary skilled artisan would indeed be motivated to generate antibodies against KIAA0849 in order to monitor the brain tissue-specific expression of the protein (in relation to the expression of the gene). Thus, Applicant's argument that there is no motivation to produce antibodies to KIAA0849 is considered non-persuasive.

***Allowable Subject Matter***

Claims 3, 39, 40, 42, 43, 47, 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.  
AU 1636



JAMES KETTER  
PRIMARY EXAMINER